IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Joseph L. Duffy, et al.

Serial No.

10/540,283

Filed: .

June 20, 2005

For:

3-AMINO-4-PHENYLBUTANOIC ACID DERIVATIVES AS DIPEPTIDYL PEPTIDASE INHIBITORS FOR THE

TREATMENT OR PREVENTION OF DIABETES

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Art Unit: _		,	
Examiner:			

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

Sir:

- 1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
- 2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
- 3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
- 4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By Tamela Spalding Date 8-17-07

RELATED APPLICATION

INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

FILING DATE	MERCK CASE
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By: Philippe L. Durette Attorney For Appl Reg. No. 35,125 MERCK & CO., INC. Patent Dept., RY60-30 P.O. Box 2000 Rahway, N.J. 07065-0907	
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Date: August 17, 2007

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]	NFORMATION I	DISCLOSURE	Application Number	10/540,283		
		A DDY YOU AND	Filing Date	June 20, 2005		
2	STATEMENT BY	APPLICANI	First Named Inventor	Joseph L. Duffy, et al.		
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Sheet	1	of 4	Attorney Docket Number	21304YP	_	

			U.S. PA	ATENT DOCUMENTS	
Examiner Initials*	Cite No.	U.S. Patent Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
	1	US 4,386,090		Moinet, et al.	05/31/1983
	2	US 5,939,560		Jenkins, et al.	08/17/1999
	3	US 6,011,155		Villhauer	01/04/2000
	4	US 6,166,063		Villhauer	12/26/2000
	5	US 6,303,661 B1		Demuth, et al	10/16/2001
-	6	US 6,429,313 B2		Carpino, et al	08/06/2002
	7	US 6,432,969 B1		Villauer	08/13/2002
	8	US 6,699,871 B2		Edmondson, et al.	03/02/2004
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			FOREIG	N PATENT	T DOCUMENTS	
Examiner Cite Initials* No.			Foreign Patent Document		N. CD.	Date of Publication of
		Office	: Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY
	1	PCT	WO 97/40832		Hans-Knoll-Institut Fur Naturstoff-Forschung E.V.	11/06/1997
	2	PCT	WO 97/30053		Biomeasure Incorporated	08/21/1997
	3	PCT	WO 98/19998		Novartis AG	05/14/1998
	4	PCT	WO 00/34241		Novartis AG	06/15/2000
	5	PCT	WO 01/34594 A1		Guilford Pharmaceuticals, Inc.	05/17/2001
	6	PCT	WO 01/42262 A2		Akzo Nobel N.V.	06/14/2001
	7	PCT	WO 01/96295 A2		Novartis AG	12/20/2001
	8	PCT	WO 02/02560 A2		Novo Nordisk A/S	01/10/2002
	9	PCT	WO 02/076450 A1		Merck & Co., Inc.	10/03/2002
	10	PCT	WO 03/000180 A2		Merck & Co., Inc.	01/03/2003

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^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	NFORMATION	DIS	CLOSURE	Application Number	10/540,283	
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2	STATEMENT BY	AP	PLICANI	First Named Inventor	Joseph L. Duffy, et al.	
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Sheet	2	of	4	Attorney Docket Number	21304YP	

U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.	U.S. Patent Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY		
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	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.	•		Kind Code	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY		
	11	PCT	WO 03/000181 A2	(if known)	Merck & Co., Inc.	01/23/2003		
	12	PCT	WO 03/004498 A1		Merck & Co., Inc.	01/16/2003		
	13	PCT	WO 03/082817 A2		Merck & Co., Inc.	10/09/2003		
	14	PCT	WO 2004/007468 A1		Merck & Co., Inc.	01/22/2004		
	15	PCT	WO 2004/032836 A2		Merck & Co., Inc.	04/22/2004		
	16	PCT	WO 2004/043940 A1		Merck & Co., Inc.	05/27/2004		
	17	PCT	WO 2004/050022 A2		Merck & Co., Inc.	06/17/2004		
	18	PCT	WO 2004/058266 A1		Merck & Co., Inc.	07/15/2004		
	19	PCT	WO 2004/064778 A2		Merck & Co., Inc.	08/05/2004		
	20	PCT	WO 2004/069162 A2		Merck & Co., Inc.	08/19/2004		

Examiner Signature	Date Considered	

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	STATEMENT BY	AP	PLICANI	First Named Inventor	Joseph L. Duffy, et al.	
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U.S. PATENT DOCUMENTS							
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FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Examiner Cite Initials* No.		Foreign Patent Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY		
	21	PCT	WO 2004/110436 A1		Merck & Co., Inc.	12/23/2004		
	22	PCT	WO 2004/112701 A2		Merck & Co., Inc.	12/29/2004		
	23	PCT	WO 2005/011581 A2		Merck & Co., Inc.	02/10/2005		
	24	PCT	WO 2005/044195 A2		Merck & Co., Inc.	05/19/2005		

Examiner Signature Date Considered

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Su	Substitute for form 1449B/PTO			COMPLETE IF KNOWN		
INFORMATION DISCLOSURE				Application Number	10/540,283	
8	TATEMENT DV	A D	DI ICANT	Filing Date	June 20, 2005	
STATEMENT BY APPLICANT				First Named Inventor	Joseph L. Duffy, et al.	
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	(use as many sheets	as n	ecessary)	Examiner Name		
Sheet	4	of	4	Attorney Docket Number	21304YP	

		NON PATENT LITERATURE DOCUMENTS
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	1	Ashworth, D. M. et al., "4-Cyanothiazolidides as very potent, stable inhibitors of dipeptidyl peptidase IV" Bioorganic & Medicinal Chemistry Letters, Vol. 6, No. 22, pp 2745-2748, 1996
	2	Augustyns, K. et al., "Dipeptidyl peptidase IV inhibitors as new therapeutic agents for the treatment of Type 2 diabetes" Expert Opin. Ther. Patents, Vol. 13, No. 4, pp. 499-510, 2003
	3	Deacon, C. F. et al., "Inhibitors of dipeptidyl peptidase IV: a novel approach for the prevention and treatment of Type 2 diabetes?" Expert Opin. Investig. Drugs, Vol. 13, No. 9, pp. 1091-1102, 2004
	4	Deacon, C. F., "Perspectives in Diabetes - Therapeutic Strategies Based on Glucagon-Like Peptide 1" Diabetes, Vol. 53, pp. 2181-2189, 2004
	5	Drucker, D. J., "Therapeutic potential of dipeptidyl peptidase IV inhibitors for the treatment of type 2 diabetes" Expert Opin. Invest. Drugs, Vol. 12, No. 1, pp. 87-100, 2003
	6	Edmondson, S. D. et al., Caplus AN 2003: 42275, P1-4, 2001
	7	Holst, J. J., "Treatment of Type 2 diabetes mellitus with agonists of the GLP-1 receptor or DPP-IV inhibitors" Expert Opin. Emerg. Drugs, Vol. 9, No. 1, pp. 155-166, 2004
	8	Holst, J. J. et al., "Glucagon-like peptide 1 and inhibitors of dipeptidyl peptidase IV in the treatment of type 2 diabetes mellitus" Current Opinion in Pharmacology, Vol. 4, pp. 589-596, 2004
	9	Knudsen, L. B., "Glucagon-like Peptide-1: The Basis of a New Clas of Treatment for Type 2 Diabetes" J. Med. Chem, Vol. 47, pp. 4128-4134, 2004
	10	Novartis AG: WO0034241 "Novel N-substituted-2-cyanopyrrolidines as potent inhibitors of dipeptidyl peptidase IV in the treatment of non-insulin-dependent diabetes mellitus" Exp. Opin. Ther. Patents, Vol. 10, No. 12, pp. 1937-1942, 2000
	11	Vahl, T. P. et al., "Gut peptides in the treatment of diabetes mellitus" Expert Opin. Investig. Drugs, Vol. 13, No. 3, pp. 177-188, 2004
	12	Weber, A. E., "Dipeptidyl Peptidase IV Inhibitors for the Treatment of Diabetes" J. Med. Chem, Vol. 47, pp. 4135-4141, 2004

Examiner Signature	Date Considered	

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P&T OFFICE ACKNOWLEDGEMENT ATTORNEY DATE Philippe L. Durette 8/17/2007 CASE NUMBER/ SERIAL NUMBER 10/540,283 21304YP DATE FILED June 20,2005 APPLICANT Joseph L. Duffy, et al. EXPRESS MAIL NO. The Patent & Trademark Office acknowledges, and has stamped hereon, the date of the receipt of the items checked below: AMENDMENT APPEAL AND FEE BRIEF CERTIFICATE OF CORRECTION FINAL FEE **LETTER** INFORMATION DISCLOSURE STATEMENT PTO 1449 & REFERENCES - 36 References PETITION FOR EXTENSION OF TIME & FEE INVITATION TO CORRECT DEMAND-CHAPTER II & FEE SHEET SEQUENCE STATEMENT SEQUENCE LISTING SEQUENCE DISKETTE